

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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HARVEY A. SILVERSTEIN and LINDA M.
SILVERSTEIN,

Plaintiff,

against-

SMITHKLINE BEECHAM CORPORATION,
GLAXOSMITHKLINE and
SMITHKLINE BEECHAM CORPORATION
d/b/a GLAXOSMITHKLINE,

Defendants.
-----x

07 CIV 8170

COMPLAINT

Plaintiff Demands
Trial by Jury

#1

Plaintiff, by attorneys, THE LANIER LAW FIRM, PLLC, as and for the undersigned
Complaint herein allege upon information and belief the following:

STATEMENT OF THE CASE

1. This is an action to recover damages for personal injuries sustained by the Plaintiff, HARVEY A. SILVERSTEIN, (hereinafter referred to as "Plaintiff"), as the direct and proximate result of the wrongful conduct of the Defendants, SMITHKLINE BEECHAM CORPORATION, GLAXOSMITHKLINE and SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, (hereinafter referred to as "Defendants" or "GSK"), in connection with the designing, developing, manufacturing, distributing, labeling, advertising, marketing, promoting, and selling of the widely-used diabetes prescription drug Avandia (rosiglitazone).

PARTIES AND JURISDICTION

2. Jurisdiction exists as against the Defendants, SMITHKLINE BEECHAM CORPORATION, GLAXOSMITHKLINE and SMITHKLINE BEECHAM CORPORATION

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SOUTHERN DISTRICT COURT
NEW YORK, N.Y.

d/b/a GLAXOSMITHKLINE, pursuant to:

(a) 28 U.S.C. Section 1332, in that the Plaintiffs, HARVEY A.

SILVERSTEIN and LINDA M. SILVERSTEIN, is a citizen and resident of the State of New York, the Defendants, SMITHKLINE BEECHAM CORPORATION, GLAXOSMITHKLINE and SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, are Pennsylvania corporations with their principal place of business and address at 1 Franklin Plaza, Philadelphia, Pennsylvania, and regularly conduct business in the State of New York, and the amount in controversy exceeds the sum of \$75,000.00 exclusive of interest and costs.

(b) 28 U.S.C. Section 1391, in that jurisdiction is founded only on diversity of citizenship, and the Judicial District of the Southern District of New York is a Judicial District in which a substantial part of the events or omissions giving rise to the claim occurred.

3. That at all times hereinafter mentioned, upon information and belief, Defendant, SMITHKLINE BEECHAM CORPORATION, was and still is a corporation organized and existing under the laws of the State of Pennsylvania.

4. That at all times hereinafter mentioned, upon information and belief, Defendant, SMITHKLINE BEECHAM CORPORATION, was and still is a foreign corporation authorized to do business in the State of New York.

5. That at all times hereinafter mentioned, upon information and belief, Defendant, SMITHKLINE BEECHAM CORPORATION, was and still is a business entity actually doing business in the State of New York.

6. That at all times hereinafter mentioned, upon information and belief, Defendant, GLAXOSMITHKLINE, was and still is a corporation organized and existing under the laws of the State of Pennsylvania.

7. That at all times hereinafter mentioned, upon information and belief, Defendant, GLAXOSMITHKLINE, was and still is a foreign corporation authorized to do business in the State of New York.

8. That at all times hereinafter mentioned, upon information and belief, Defendant, GLAXOSMITHKLINE, was and still is a business entity actually doing business in the State of New York.

9. That at all times hereinafter mentioned, upon information and belief, Defendant, SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, was and still is a corporation organized and existing under the laws of the State of Pennsylvania.

10. That at all times hereinafter mentioned, upon information and belief, Defendant, SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, was and still is a foreign corporation authorized to do business in the State of New York.

11. That at all times hereinafter mentioned, upon information and belief, Defendant, SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, was and still is a business entity actually doing business in the State of New York.

13. That at all times hereinafter mentioned, upon information and belief, Defendants presently markets and sells the drug Avandia.

14. That since May 25, 1999, Defendants marketed and sold the drug Avandia.

15. That at all times hereinafter mentioned, upon information and belief, Defendants engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs, including Avandia, and in pursuance of this business, transacts business within the State of New York and contracts to provide goods and services in the State of New York.

16. That at all times hereinafter mentioned, upon information and belief, Defendants committed a tortious act, which caused injury to Plaintiff, resident the State New York.

17. That at all times hereinafter mentioned, upon information and belief, Defendants committed a tortious act outside the State of New York, which caused injury to Plaintiff, resident of the State of New York.

18. That at all times hereinafter mentioned, upon information and belief, Defendants regularly does and solicits business and engages in a persistent course of conduct in the State of New York, deriving substantial revenue from goods and products consumed in the State of New York.

19. That at all times hereinafter mentioned, upon information and belief, Defendants expects or should reasonably expect its acts to have consequences in the State of New York, and derives substantial revenue from interstate or international commerce.

**BACKGROUND
STATEMENT OF THE CASE**

20. Type 2 diabetes is the most common form of diabetes, afflicting 18 million Americans and 200 million people worldwide. This form of diabetes occurs when the body does not make enough insulin (a hormone needed to convert sugar and other food into energy) or cannot effectively use what it manages to produce. Further, diabetics are prone to heart problems, and indeed, two-thirds of diabetics die of heart problems.

21. Avandia, created and marketed by GSK, is designed to treat persons with Type 2 diabetes by helping sensitize cells to insulin, thereby greatly assisting in blood-sugar control. It also is combined with metformin and sold as Advandamet. Only one other drug like it, pioglitazone, sold as Actos and Actoplus, Met by Takeda Pharmaceuticals, is sold in the

United States. In 2006, Advandia represented 37% of the U.S. market for oral diabetes treatments. Thus, the U.S. market for such drugs is huge, and Advandia faces only one competitor for that market.

22. Advandia had a total U.S. sales of \$2.2 billion in 2006, slightly less than the \$2.6 billion in total U.S. sales for Actos, according to IMS Health, a healthcare information company. Approximately 13 million Advandia prescriptions were filled in the U.S. last year, with a one-month supply of Advandia selling for between \$90 and \$170. Advandia is critical to GSK, being the company's second largest selling drug after Advair (an asthma medication).

23. GSK's product Advandia can cause heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure and severe injury to the heart leading to cardiac arrest and death. In 2005, GSK performed an overview analysis of multiple Advandia trials, referred to as a "meta-analysis", and shared the preliminary results with the Food and Drug Administration ("FDA") in September 2005. Almost one year later, in August 2006, a more complete version of the meta-analysis was provided to the FDA. The results of GSK's analysis showed that patients taking Advandia had a 31% higher risk of adverse cardiovascular events such as heart attack due to obstruction of blood flow.

24. GSK's Advandia can cause heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure, and severe injury to the heart leading to cardiac arrest and death. Not only was GSK aware of the dangers posed by Advandia, but data from these studies continued to be made available to GSK. On May 21, 2007, Dr. Steven E. Nissen, a prominent cardiologist associated with the Cleveland Clinic, published a study in the *New England Journal of Medicine* of his analysis of 42 studies comprising of approximately 28,000 people who took Advandia. These were on-line databases of GSK studies that were available on the

Internet. Dr. Nissen's meta-analysis revealed a 43% higher risk of heart attack for those taking Avandia compared to people taking other diabetes drugs or no diabetes medication, and people taking Avandia suffered such adverse events at a rate of 1.99%, as opposed to 1.51% for other patients. Further, Dr. Nissen's analysis showed a 64% elevated risk of death from cardiovascular causes.

25. Despite GSK's longstanding knowledge of these dangers, Avandia's label only warns about possible heart failure and other heart problems when taken with insulin. GSK failed to warn and disclose to consumers that Avandia significantly increased the risk of adverse cardiovascular events. Furthermore, the proper and effective use of Avandia by Plaintiff was impaired due to GSK's failure to warn of Avandia's defects and GSK's failure to properly and adequately set forth such warnings in Avandia's drug labeling.

26. GSK knew of these dangerous defects in Avandia from the many trials which it performed and to which it had access and from its own analysis of these studies, but took no action to adequately warn or remedy the defects, but instead concealed, suppressed and failed to disclose these dangers. Even in the face of Dr. Nissen's study, GSK continues to fail to warn of these dangers through revised drug labeling.

27. Not only has GSK failed to disclose in its labeling or advertising that Avandia is actually dangerous for diabetics, GSK has represented and continues to represent that they manufacture and/or sell safe and dependable pharmaceuticals with safety as their first concern:

Like all innovative pharmaceutical companies, we carry out a series of clinical trials to test each investigational drug for the potential to become a new medicine.

* * *

Phase I trials typically involve health volunteers. *These trials study the safety of the drug and its interaction with the body*, for example, its concentration and

duration in the blood following various doses, and begin to answer such questions as whether the drug inhibits or amplifies the effects of other medicines that might be taken at the same time.

Phase II studies enroll patients with the illness an investigational drug is designed to treat. These trials evaluate whether the drug shows favourable effects in treating an illness and seek to determine the proper dose. They provide an opportunity to explore the therapeutic potential of the drug in what may be quite different illnesses. *The evaluation of safety continues.*

If Phase II results have been encouraging, Phase III trials, the largest part of a clinical-development program, go forward. *Phase III trials are designed to provide the substantial evidence of efficacy and safety required*, in addition to data from earlier-phase trials, before regulatory agencies will approve the investigational drug as a medicine and allow it to be marketed.

<http://www.gsk.com/research/clinical/index/html> (emphasis supplied).

28. GSK has also strongly touted their commitment to improving the quality of life: “We have a challenging and inspiring mission: to improve the quality of human life by enabling people to do more, feel better and live longer.” <http://www.gsk.com/about/index.htm>.

29. On May 21, 2007, the FDA issued a Safety Alert on Avandia showing that there is a potentially significant risk of heart attack and heart-related deaths in patients taking Avandia.

30. Based on these representations, upon which Plaintiff relied, including the omission from the Avandia labeling of the danger of increased risk of adverse cardiovascular events as a result of ingesting Avandia, Plaintiff purchased and ingested Avandia believing that the drug would be safe and effective.

31. In fact, however, Avandia poses significant safety risks due to defects in its chemical design and inadequate labeling.

32. To date, GSK has failed to warn or inform consumers, such as Plaintiff or Plaintiff’s prescribing physician, of the known defects in Avandia that can lead to increased

risks of cardiovascular events, including myocardial infarction, fraudulently concealed these defects and made misrepresentations to the damage and detriment of Plaintiff.

33. As a result of GSK's omissions and/or misrepresentations, Plaintiff FRANK W. CURLEY ingested Avandia from approximately September 1999 to October 2005.

34. On or around April 11, 2006, Plaintiff HARVEY A. SILVERSTEIN suffered a myocardial infarction.

35. As alleged herein, as a direct and proximate result of the Defendants' negligence and wrongful conduct, and the unreasonably dangerous and defective characteristics of the subject product, the Plaintiff HARVEY A. SILVERSTEIN suffered severe and permanent physical injuries, including not limited to a myocardial infarction. The Plaintiff has endured substantial pain and suffering. He has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. The Plaintiff HARVEY A. SILVERSTEIN has lost past earnings and has suffered a loss of earning capacity. The Plaintiff HARVEY A. SILVERSTEIN has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. The Plaintiff HARVEY A. SILVERSTEIN injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual punitive damages from the Defendants as alleged herein.

**AS AND FOR A FIRST CAUSE OF ACTION
AGAINST DEFENDANTS FOR NEGLIGENCE**

36. Plaintiff repeats and reiterates the allegations previously set forth herein.

37. That at all times hereinafter mentioned, Defendants was under a duty to exercise

reasonable care in the design manufacture, testing processing, marketing advertising, labeling, packaging distribution, and sale of Avandia, and Defendants knew or should have known that Avandia was not safe and that the user could sustain injuries and harm from the drug.

38. That Defendants negligently, recklessly, grossly negligently, wantonly and willfully displayed a morally culpable and conscious disregard of the rights of others in that they failed to exercise reasonable care and failed to fulfill the above-stated duty by the manner that Defendants, directly and indirectly, advertised, marketed and promoted Avandia for the treatment of diabetes, even though Avandia, in fact, not reasonably safe for such use, and furthermore, Defendants failed to adequately warn of the increased risk of serious cardiovascular events which Defendants knew or should have known about.

39. That Defendants was further negligent, reckless, grossly negligent, wanton and willfully displayed a morally culpable and conscious disregard of the rights of others by manufacturing, distributing, selling, advertising, marketing and promoting Avandia even though such drug was not safe or effective for any purpose because it caused serious cardiovascular events and by failing to adequately warn the public of such risks.

40. The aforesaid incident and the injuries sustained by Plaintiff were caused by or were contributed to by the negligence, recklessness, gross negligence, wantonness, willfulness, and conscious and callous disregard of the safety of the public, including Plaintiff, on the part of Defendants in the design, manufacture, distribution, advertising, marketing and promoting of Avandia as being safe and effective in the treatment of diabetes, and by inducing the public, including Plaintiff, and Plaintiff's prescribing physician, to believe that Avandia was effective in the treatment of the causes and symptoms of diabetes.

41. Defendants failed to exercise reasonable care in the design, manufacture,

testing, processing, marketing, advertising, labeling, packaging, rebranding, distribution and/or sale of Avandia in one or more of the following respects:

- a) Designing, marketing, processing, advertising, packaging, distributing and/or selling a product that defendants knew, or should have known, carried the risk of serious; life-threatening side effects;
- b) Failure to adequately test the product prior to placing the drug Avandia on the market;
- c) Failure to use care in designing, developing and manufacturing their product so as to avoid posing unnecessary health risks to users of such product;
- d) Failure to conduct adequate pre-clinical testing and post-marketing surveillance to determine the safety of Avandia;
- e) Failure to advise consumers, such as plaintiff, that consumption of Avandia could result in severe and disabling side effects, including but not limited to heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure and severe injury to the heart leading to cardiac arrest and death.
- f) Failure to advise the medical and scientific communities of the potential for severe and disabling side effects, including but not limited to heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure, and severe injury to the heart leading to cardiac arrest, and death.
- g) Failure to provide timely and/or adequate warnings about the potential health risks associated with the use of Avandia; and
- h) Any and all other acts of negligence with respect to Avandia which may be shown at trial.

42. That at all times hereinafter mentioned, upon information and belief, the above-described culpable conduct by Defendants was a proximate cause of injuries sustained by Plaintiff.

43. That at all times hereinafter mentioned, Plaintiff did not contribute to his injuries by reason of any negligence or culpable conduct on his part.

44. That as a result of the aforesaid occurrence, the injuries sustained by Plaintiff resulting therefrom, Plaintiff suffered extensive monetary and pecuniary losses and other compensatory damages were also incurred and paid out including necessary medical, hospital, and concomitant expenses. In addition, Plaintiff was deprived of a chance for safe and effective and/or successful treatment.

45. By reason of the foregoing, Plaintiff sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

**AS AND FOR A SECOND CAUSE OF ACTION
AGAINST DEFENDANTS FOR BREACH OF WARRANTY**

46. Plaintiff repeats and reiterates the allegations previously set forth herein.

47. That at all times hereinafter mentioned, upon information and belief, Defendants, by directly and indirectly advertising, marketing and promoting Avandia for the treatment of diabetes, and by placing this drug in the stream of commerce knowing that Avandia would be prescribed for the treatment of diabetes, in reliance upon the representations of Defendants, expressly warranted to all foreseeable users of this drug, including Plaintiff, that Avandia was safe and effective for the treatment of diabetes.

48. That Defendants impliedly warranted in manufacturing, distributing, selling, advertising, marketing and promoting Avandia to all foreseeable users, including Plaintiff, that Avandia was safe and effective for the purposes for which it had been placed in the stream of commerce by Defendants, including for the treatment of diabetes, and that Avandia was reasonably safe, proper, merchantable and fit for the intended purposes, including for the treatment of diabetes.

49. That at all times hereinafter mentioned, Plaintiff relied upon the aforesaid express and implied warranties by Defendants.

50. That at all times hereinafter mentioned, Plaintiff's use of Avandia prior to and up to the time of the above-described incident was consistent with the purposes for which Defendants directly and indirectly advertised, marketed and promoted Avandia, and Plaintiff's use of Avandia was reasonably contemplated, intended and foreseen by Defendants at the time of the distribution and sale of Avandia by Defendant, and, therefore, Plaintiff's use of Avandia was within the scope of the above-described express and implied warranties.

51. Defendants breached the aforesaid express and implied warranties because Avandia was not safe and effective for the treatment of diabetes, and because Plaintiff's use of Avandia for the treatment of diabetes, caused or contributed to the incident described herein.

52. Plaintiff gave appropriate notice to Defendants of the breach of the aforesaid express and implied warranties or such notice was otherwise excused.

53. By reason of the foregoing, Plaintiff sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

**AS AND FOR A THIRD CAUSE OF ACTION
AGAINST DEFENDANTS FOR STRICT PRODUCTS LIABILITY**

54. Plaintiff repeats and reiterates the allegations previously set forth herein.

55. That at all times hereinafter mentioned, the drug Avandia was not suited for the treatment of diabetes, and was not safe and effective for the treatment of diabetes, even though Defendants directly and indirectly advertised, marketed and promoted Avandia for such use.

56. That at all times hereinafter mentioned, the drug Avandia was not safe and was

not suited for the purposes for which Defendants, directly and indirectly, advertised, marketed and promoted the drug at the time Defendants designed, manufactured, distributed and sold the drug and placed the drug in the stream of commerce.

57. Avandia was defective and unreasonably dangerous when it left control of Defendants in one or more of the following manners:

- a) The risk associated with use of Avandia far outweighed the utility derived from using the medication;
- b) Defendants failed to provide adequate warnings regarding the hazards associated with the use of Avandia;
- c) Defendants product was defectively designed and unreasonably dangerous in design and composition in that other medications could achieve similar results without the risks presented by Avandia; and
- d) Avandia failed to comply with express warranties that the product was safe and effective for human consumption.

58. Defendants were in the business of designing, developing, manufacturing, rebranding, labeling, marketing, distributing and/or selling Avandia.

59. Defendants sold and/or distributed Avandia in a condition that posed unreasonable risks from reasonably anticipated use. Avandia was expected to and did reach Plaintiff without substantial change in condition from the time that it left the control of Defendants.

60. The defective conditions alleged herein rendered Avandia unreasonably dangerous to Plaintiff and proximately caused the injuries and damages for which this lawsuit seeks recovery.

61. The Avandia ingested by Plaintiff was defective and unreasonably dangerous when it left the control of Defendants.

62. The unreasonably dangerous characteristics of Avandia proximately caused the

injuries and damages for which recovery is sought.

63. Defendants knew, or in the light of reasonably available knowledge, should have known, of the danger in Avandia that caused the damage for which recovery is sought. The ordinary user or consumer of Avandia would not realized such dangers.

64. Defendants neglected to provide Plaintiff with warnings that reasonably could have been expected to catch the attention of a reasonably prudent person under similar circumstances taking into account the characteristics of, and the ordinary knowledge common to an ordinary consumer who purchases the product. Further, Defendants failed to provide warnings which could accurately advise and ordinary consumer of the scope, severity and likelihood of serious injury resulting from use of its product. Had such warnings been provided, the injuries and damages sustained by Plaintiff could have been avoided.

65. Defendants neglected to provide Plaintiff's prescribing physician with adequate warnings to accurately advise such physician of the increased severity and likelihood of serious injury resulting from the prescribing and ingestion of Avandia to patients such as Plaintiff.

66. Defendants product failed to function as expected and there existed feasible design alternatives equally effective and useful that would have had a reasonable probability of preventing the harms sustained by Plaintiff.

67. That at all times hereinafter mentioned, upon information and belief, Defendants assumed a strict products liability to users and to persons using Avandia, including Plaintiff, who sustained injuries, harm and damages by reason of the use of Avandia for purposes directly and indirectly advertised, marketed, and promoted by Defendants, including for the treatment of diabetes.

68. By reason of the foregoing, Plaintiff sustained damages in a sum which exceeds

the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

**AS AND FOR A FOURTH CAUSE OF ACTION
AGAINST DEFENDANTS FOR FRAUDULENT MISREPRESENTATION**

69. Plaintiff repeats and reiterates the allegations previously set forth herein

Defendants widely advertised and promoted Avandia as a safe and effective medication.

70. Defendants had a duty to disclose material information about serious side effects to consumers such as Plaintiff. Additionally by virtue of Defendant's partial disclosures about the medication, in which Defendants touted Avandia as safe and effective treatment, Defendants had a duty to disclose all facts about the risks of use associated with the medication, including the potential for the medication to cause heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure, and severe injury to the heart leading to cardiac arrest, and death. Defendants intentionally failed to disclose this information for the purpose of inducing consumers, such as Plaintiff, to purchase Defendant's dangerous product.

71. Had Plaintiff been aware of the hazards associated with Avandia, Plaintiff would not have consumed the product that lead proximately to Plaintiff's adverse health effects.

72. Defendant's advertisements regarding Avandia made material misrepresentations to the effect that Avandia was a safe and effective treatment, which misrepresentations Defendants knew to be false, for the purpose of fraudulently inducing consumers, such as Plaintiff, to purchase such product. Plaintiff relied on these material

misrepresentations in deciding to purchase and consume Avandia to his detriment.

73. The damages sustained by Plaintiff was a direct and foreseeable result of, and were proximately caused by Defendants misrepresentations, concealment and omissions.

74. Defendants conduct was willful, wanton, and reckless. Based on the intentionally dishonesty nature of Defendants conduct, which was directed at Plaintiff and the public generally, Defendants should also be held liable for punitive damages.

75. Any applicable statutes of limitation have been tolled by Defendants knowing and active concealment and denial of the facts alleged herein. Plaintiff and other members of the public who were prescribed and ingested Avandia for the treatment of diabetes have been kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part, and could not reasonably have discovered the fraudulent nature of Defendants conduct, and information and documents concerning the safety and efficacy of Avandia. Plaintiff may also rely on a tolling agreement with SMITHKLINE BEECHAM CORPORATION. Furthermore, due to the aforesaid allegations, Plaintiff may rely on the discovery rule in pursuit of this claim.

76. By reason of the foregoing, Plaintiff sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

**AS AND FOR A FIFTH CAUSE OF ACTION
AGAINST DEFENDANTS FOR VIOLATIONS OF
NEW YORK GENERAL BUSINESS LAW §§ 349 AND 350**

77. Plaintiff repeats and reiterates the allegations previously set forth herein.

78. Defendants acted, used and employed deception, unfair and deceptive acts and

practices, fraud, false promises, misrepresentations, concealment, suppression and omission of material facts with intent that physicians and medical providers rely upon such concealment, suppression and omission, and for the purpose of influencing and inducing physicians and medical providers to prescribe Avandia, for the treatment of diabetes to patients/consumers such as Plaintiff, and causing such patients/consumers to purchase, acquire and use Avandia for the treatment of diabetes, as prescribed by their physicians and medical providers, in connection with the sale and advertisement of the drug Avandia, in violation of New York General Business Law §§ 349 and 350.

79. By reason of Defendants acts, uses and employment of deception, unfair and deceptive acts and practices, fraud, false promises, misrepresentations, concealment, suppression and omission of material facts, reasonable patients/consumers acting reasonably, such as Plaintiff, were caused to purchase and ingest Avandia, and thereby sustain serious personal injuries.

80. By reason of the facts and premises aforesaid, Plaintiff was damaged in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter, costs and reasonable attorneys fees.

**AS FOR THE SIXTH CAUSE OF ACTION
AGAINST DEFENDANTS FOR NEGLIGENCE PER SE**

81. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

82. Defendants have an obligation not to violate the law.

83. Defendants have violated the Federal Food, Drug and Cosmetic Act, 21, U.S.C. 301, *et Seq.*, related amendments and codes and federal regulations promulgated thereunder, and other applicable state and federal laws.

84. Plaintiff, as a purchaser and consumer of Avandia, is within the class of persons that statutes described above are designed to protect.

85. Injury due to false, misleading and/or reckless advertising and promotion, and misbranding, misleading products and as otherwise set forth in this complaint, is the specific type of harm these statutes are designed to prevent.

86. Defendants are responsible to plaintiff for injuries incurred for their violations of the statutes described above under the doctrine of negligence per se.

87. As a direct and proximate result of the negligence and negligence per se of the defendants and each one individually and as a result of the defendants' actions and/or inactions as set forth in this complaint, Plaintiff was caused to suffer the serious and dangerous side effect of a myocardial infarction, as well as other severe and personal injuries which are permanent and lasting in nature, including but not limited to physical pain and mental anguish, diminished enjoyment of life, and any and all life complications such as Plaintiff's need for lifelong medical treatment, monitoring and/or medications, and to incur related expenses, including but not limited to, loss of earnings and/or other costs as the proof will demonstrate, and the plaintiff demands all damages to which the plaintiff is entitled under the law in an amount deemed fair and reasonable.

88. The limitations on liability set forth in CPLR Section 1601 do not apply to this action by reason of one or more of the exceptions set forth in CPLR Section 1602.

**AS AND FOR A SEVENTH CAUSE OF ACTION
AGAINST DEFENDANTS FOR LOSS OF CONSORTIUM**

89. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.

90. Plaintiff HARVEY A. SILVERSTEIN's spouse, LINDA M. SILVERSTEIN was at *all times* relevant herein the wife of, and as such, lives and cohabits with Plaintiff HARVEY A. SILVERSTEIN.

91. By reason of the foregoing, Plaintiff's spouse has necessarily paid and has become liable to pay for medical aid, treatment, attendance, and for medications, and will necessarily incur further expenses of a similar nature in the future.

92. By reason of the foregoing, Plaintiff's spouse has been caused, presently and in the future the loss of his wife's companionship, services, society and the ability of said Plaintiff's spouse in said respects has been impaired, and depreciated, and the marital association between husband and wife has been altered, and as such the Plaintiff's spouse has been caused great mental anguish and suffering.

93. Plaintiffs demand judgment against each Defendant individually and/or jointly for compensatory damages and punitive damages together with interest, costs of suit and attorneys' fees and such other relief as the Court deems proper

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

(1) The sum of \$100,000,000.00 on the First Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(2) The sum of \$100,000,000.00 on the Second Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(3) The sum of \$100,000,000.00 on the Third Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(4) The sum of \$100,000,000.00 on the Fourth Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action; and

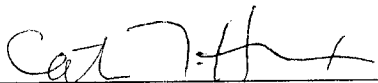
(5) A sum which exceeds the jurisdictional limits of all lower courts which the jury would find to be fair, adequate and just on the Fifth Cause of Action, and in addition, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter, together with costs and reasonable attorneys fees.

DEMAND FOR JURY TRIAL

Plaintiff demands a jury trial on all claims so triable in this action.

Dated: September 14, 2007

THE LANIER LAW FIRM, PLLC
Attorneys for Plaintiff
126 East 56th Street, 6th Floor
New York, New York 10022

BY: 
CATHERINE T. HEACOX, ESQ.

TO: SMITHKLINE BEECHAM CORPORATION
GLAXOSMITHKLINE and
SMITHKLINE BEECHMAN CORPORATION
d/b/a GLAXOSMITHKLINE
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